

REMARKS

Claims 7-24 are pending in the present application. Applicants thank the Examiner for the removal of the rejection over Pariza. The following rejections are at issue and are set forth by number in the order in which they are addressed:

- 1) Claims 7-24 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cain et al. (WO 97/18320); and
- 2) Claims 7-24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being nonenabled.

1. The Claims are not obvious

A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue.¹ In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent there from.² Applicants respectfully Cain does not teach each element of the invention as claimed.

As previously argued and addressed in detail below, the Declaration of Mr. Asgeir Sæbo establishes that the product obtained by Cain necessarily contained greater than 1% of the 8,10 and 11,13 isomers of CLA (octadecadienoic acid). The Examiner's interpretation of the data presented in the Declaration and the surrounding legal issues appear to be misguided.

a. The data in the Declaration is directly relevant to the claims

In paragraph 4 of the Office Action, the Examiner states that:

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

² §MPEP 2143.03.

[I]t is noted that the instantly filed claims are only directed to an isomerized conjugated linoleic acid composition that are comprised of at least 50% "9,11-octadecadienoic acid and 10,12 octadecadienoic acid" with less than 1% of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid expressed as peak area percentages. . . . Because the instant claims do not distinguish particular geometric isomers of linoleic acid the claims are not limited to any particular geometric isomers, and so the arguments regarding the Sæbo declaration are not germane to the instantly filed claims."

Applicants fail to understand this argument. The Sæbo Declaration established the presence of the 8,10 and 11,13 isomers in compositions made by the Cain process. In particular, Mr. Sæbo states that the Cain method "resulted in a conjugated linoleic acid composition comprising approximately 3.49% c11,t13 CLA and 2.24% t9,t11and t10,t12 CLA." The Claims require that the compositions contain less than 1% 11,13 and 8,10 isomers. Thus, Mr. Sæbo establishes that the Cain method produces a product that does not meet the claimed element of "less than 1% 11,13 and 8,10 isomers." It is noted that the claim term "11,13 isomer" defines a class of isomers including the 4 possible geometric isomers of 11,13 octadecadienoic acid (i.e., c11,t13; t11,c13; c11,c13; t11,t13). Thus, the issue of geometric isomers is irrelevant to the claims and the data in the Declaration. In other words, the data in the Declaration supports the claims in all aspects.

b. Applicant's use of the term "comprising" is proper

The Examiner also raises an unfounded issue with respect to the term comprising:

Furthermore, applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim." . . . Accordingly, these claims are open-ended and thus do not rule of the presence of other components or isomers, which would clearly embrace other isomers of CLA.

Applicants do not dispute the meaning of the claim term comprising. However, the claims specify that the compositions contain **less than** 1% 8,10 and 11,13 isomers. Thus, the claims specifically exclude greater amounts of these particular isomers. In other words, the claims are not open-ended with respect to the isomers. Thus, the claims distinguish over the compositions of Cain, which necessarily contained greater than 1% of the 8,10 and 11,13 isomers. By way of analogy, a car having four wheels does not provide each element of a claim that states a vehicle

comprising two or fewer wheels. The limitation two or fewer wheels does not encompass four wheels even though the term comprising is used.

c. The Examiner has misinterpreted the data in the Declaration

Applicants further submit that the Examiner's calculations in paragraph 5 are flawed and evince a misunderstanding of the data. Mr. Sæbo states in the Declaration that: "The t8,c10 isomer co-elutes with the c9,t11 isomers, **but almost always occurs in a one to one proportion to the c11,t13 isomer.**" (Emphasis added). Thus, since the c11,t13 isomers is present at 3.49%, the t8,c10 isomer would be present at approximately 3.49%. The Examiner's calculations are flawed because they are based on the 8,10 isomer occurring in equal proportion to the c9,t11 isomer, not the c11,t13 isomer as stated in the Declaration. This fundamental error affects the rest of the Examiner's calculations as well.

Furthermore, Applicants must emphasize that the even if the Examiner's calculation were correct, Cain would not provide each element of the Claims because Cain fails to provide compositions with than 1% of the 8,10 and 11,13 isomers. Even if the compositions of Cain do contain greater than 50% 9,11 and 10,12 isomers, they still fail to contain less than 1% of the 8,10 and 11,13 isomers.

d. The Examiner's sigmatropic rearrangement analysis is complete hindsight reconstruction

In paragraph 7 of the Office Action, the Examiner states that "it would have been obvious to the skilled artisan to decrease the temperatures in order to control the production of sigmatropic products, namely the 8,10- and 11,13-octadecadienoic acid isomers."

This statement is completely unsupported by any reference to prior art that establishes the conjugated bond system of octadecadienoic acid is a sigmatropic system! The only evidence cited by the examiner is from the Solomons textbook, which says nothing about the behavior of the conjugated bonds of octadecadienoic acid. Furthermore, analysis of the specification indicates that the claimed result of less than 1% 8,10 and 11,13 isomers is not just a function of heat as indicated by the examiner, but a function of the combined effects of pressure, time, solvent and catalyst as well. See, for example, Specification, page 8, lines 5-11 and page 11, lines 11-15. Furthermore, the reduction of the amount of the 8,10 and 11,13 isomers must be balanced with efficiency of conversion of the linoleic acid to the desired t10,c12 and c9,t11 isomers. The Examiner's analysis completely ignores these constraints and focuses only on heat.

Applicants further note that the only place the Examiner could have developed this argument from is the Applicants own disclosure, both in the form of the specification and Declaration of Mr. Sæbo which refers to a book chapter that is not prior art. Thus, the Examiner has derived his argument solely from the disclosure of the Applicants. The fact is that the instant application teaches controlling heat, pressure, time, solvent and catalyst to achieve a particular CLA composition. The cited prior art, whether Cain or Solomons or both taken together, do not teach these steps applied to the production of CLA or the production of CLA with the claimed properties. The Examiner states in paragraph 6 that motivation to decrease the amounts of the 8,10 and 11,13 isomers is provided by Cain because the 9,11 and 10,12 isomers "are responsible for the beneficial effects of the compositions containing CLA". However, Cain does not provide any guidance as to increase the amounts of the desirable isomers or indicate that CLA compositions of a higher purity with respect to the 9,11 and 10,12 isomers would have any beneficial effects as compared to less pure compositions. Motivation to modify Cain cannot be derived from the complete absence of any reference to the 8,10 and 11,13 isomers or why it would be beneficial to remove these isomers.

Because Cain is completely silent as to why reduction of the 11,13 and 8,10 isomers is desirable, it is apparent that the Examiner is relying completely on hind-sight reconstruction to reject the claims. The Federal Circuit explicitly prohibits hindsight reconstruction:

It is impermissible to first ascertain factually what appellants *did* and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants invention from such prior art.

Interconnect Planning Corp., v. Feil, 774 F2d 1132, 1143, 227 USPQ 543, 550 (Fed. Cir. 1985) (emphasis in the case) (quoting *In re Shuman*, 361 F.2d 1008, 1012, 150 USPQ 54, 57 (CCPA 1966)).

The relevant analysis should be conducted as follows:

Not only must the claimed invention as a whole be evaluated, but so also must the references, as a whole, so that their teachings are applied in the context of their significance to a technician at the time -- a technician **without our knowledge of the solution.**" (emphasis added).

Id. In other words: the prior art teaching must be considered without the benefit of hindsight, in the context of their significance at the time, without benefit of knowledge of the solution

conferred by the claimed invention.

The Examiner has fallen into the hindsight trap. A technician without knowledge of the solution taught in the instant application would not read Cain and realize whether that a) it is beneficial to reduce amounts of the 8,10 and 11,13 isomers or b) that the amounts of these isomers could be reduced through a combination of controlling time, temperature, pressure, solvent and catalyst. The only suggestion of a or b comes from the Applicants because Cain is silent with respect to the 8,10 and 11,13 isomers.

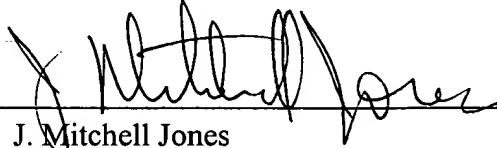
2. The enablement rejection is moot

Claims 7-24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being nonenabled. Applicants must respectfully disagree with this rejection as the specification teaches the production of a variety of isomers of CLA, including various species of the 9,11 and 10,12 isomers of CLA such as c10,c12, c9,c11, t10,t12 and t9,t11. Thus, if 9,11 CLA and 10,12 CLA are viewed as classes comprising various geometric isomers of CLA, the class is more than enabled by the disclosure of compositions containing the various species of geometric isomers within the classes. Nevertheless, Applicants respectfully submit that this rejection is moot in view of the amendments to the claims. These amendments were made without prejudice, in order to further the business interests of the applicants and should not be viewed as limiting the claims of any related applications that have issued, are currently pending, or which will be filed in the future.

Conclusion

All grounds of rejection and objection of the Office Action of February 13, 2004 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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